Special Session ImmunoBiologics in Aquaculture

"Scoping Out the Current and Future Needs of Vaccines, Bacterins and Other Immunostimulants for Aquaculture Industries"

JSA Working Group on Quality Assurance in Aquaculture Production, Biologics Subgroup

August 1, 2005 9:00 am – 4:30 pm

Bozeman Fish Technology Center, Bozeman, Montana

In conjunction with the 11^{th} Annual FWS-USGS Drug Coordination Workshop August $2-4,\,2005$

Objectives

The need for aquatic animal vaccines, bacterins and other immunostimulants for preventing (or at least minimizing the effects of) disease and/or infection is rapidly increasing. However, in the U.S. relatively few such tools are available, few researchers and producers fully understand how these products work or how they are optimally used in aquatic animals. In addition, there is no coordinated industry/agency focus on the use and/or federal licensing of such products. Pharmaceutical companies have shown some interest but few research facilities recognize and understand the options and opportunities that exist for producing, testing and licensing these products for use in aquatic animals.

This special session is being convened to create a forum to share information on the status, needs, uses, licensing processes and opportunities for immunobiologics in aquaculture, and develop possible future directions for encouraging their production, use, and availability. This session is a consequence of discussions of the federal coordinating Joint Subcommittee on Aquaculture's Working Group on Quality Assurance in Aquaculture Production. As a result of these discussions, a subgroup was formed to integrate a biologics component into their strategic planning framework with identified objectives and implementation plans, similar to long-standing approaches taken with FDA-CVM and diverse stakeholders for aquatic animal drugs.

As is the practice of the JSA Working Group on Quality Assurance in Aquaculture Production, this special session is open to all with an interest in the subject, and specifically to those who may be interested in contributing to future activities associated with supporting research and advancing the licensing of biologics for aquaculture.

Agenda (Tom Bell/David Scarfe – Moderators)

9:00 – 12:00	Participant Introductions/Presentations
Melisse Schilling	Introductory Overview
Philip Klesius	"Development and Use of Immunobiologics for Aquatic Animals"
David Starling	"Immunity and Immunological Responses in Aquatic Invertebrates and Vertebrates"
Hugh Mitchell	"Past, Present and Future of Fish Immunobiologics in Aquaculture"
Melisse Schilling	"Current U.S. Processes for Licensing Immunobiologics in the U.S."

12:00 - 1:00 Lunch

1:00 – 3:00 Roundtable Discussion

Discussion Topics:

- Future U.S. aquaculture industry needs
- Future research needs
- Research funding sources
- Licensing and regulatory issues
- Coordination of efforts: Processes and mechanisms to accelerate the availability of licensed immunobiologics
- Future educational and research forums, conferences and symposia

3:00 – 4:30 **Roundtable Conclusions**

Outlines and Plans for future:

- Education programs
 - o Aquaculture America 2006 (Las Vegas, February 13-16) Special Session
- Research programs
- Report for Wednesday's "Biologics in Aquaculture" session (1:15-3:00 pm)

<u>Individuals interested in attending are requested to inform:</u>

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